

# FEE TRANSMITTAL

Patent fees are subject to annual revision.

## Complete if Known

Application Number	09/835,694
Filing Date	April 16, 2001
First Named Inventor	Donnelly et al.
Examiner Name	Garvey, Tara L.
Group Art Unit	1636
Attorney Docket Number	18972PCA

TOTAL AMOUNT OF PAYMENT \$180

## METHOD OF PAYMENT

☒ Deposit Account

Deposit Account Number 13-2755

Deposit Account Name Merck & Co., Inc.

The Director is authorized to:

☒ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) during the pendency of this application

## FEE CALCULATION

### 1. BASIC FILING FEE

Large Fee Code	Entity Fee (\$)	Fee Description	Fee Paid
1001	790	Utility filing fee	
1002	350	Design filing fee	
1004	790	Reissue filing fee	
1005	160	Provisional filing fee	
SUBTOTAL(1)			\$0

### 2. EXTRA CLAIM FEES

	Extra	Fee from below	Fee Paid
Total Claims	20	0	0
Independent Claims	3	0	0
Multiple Dependent Claims		\$300	

\*\*or number previously paid, if greater; For Reissues, see below

Large Fee Code	Entity Fee (\$)	Fee Description	Fee Paid
1202	18	Claims in excess of 20	
1201	88	Independent claims in excess of 3	
1203	300	Multiple dependent claim, if not paid	
1204	88	**Reissue independent claims over original patent	
1205	18	**Reissue claims in excess of 20 and over original patent	
SUBTOTAL(2)			\$0

### 3. ADDITIONAL FEES

Large Fee Code	Entity Fee (\$)	Fee Description	Fee Paid
1051	130	Surcharge - late filing fee or oath	
1053	130	Non-English specification	
1812	2,520	For filing a request for <i>ex parte</i> reexamination	
1251	110	Extension for reply within first month	
1252	430	Extension for reply within second month	
1253	980	Extension for reply within third month	
1254	1,530	Extension for reply within fourth month	
1255	2,080	Extension for reply within fifth month	
1401	340	Notice of Appeal	
1402	340	Filing a brief in support of an appeal	
1403	300	Request for oral hearing	
1452	110	Petition to revive - unavoidable	
1453	1,370	Petition to revive - unintentional	
1501	1,370	Utility issue fee (or reissue)	
1502	490	Design issue fee	
1460	130	Petitions to the Commissioner	
1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	Submission of Information Disclosure Statement	180
8021	40	Recording each patent assignment per property (times number of properties)	
1809	790	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	790	For each additional invention to be examined (37 CFR 1.129(b))	
1801	790	Request for Continued Examination (RCE)	
Other fee (specify)			
Other fee (specify)			
SUBTOTAL(3)			\$180

## SUBMITTED BY

## Complete (if applicable)

Typed or Printed Name	J. Mark Hand	Reg. Number	36,545
Signature		Deposit Account User ID	
Date	12/10/04		

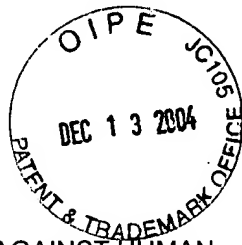
IN DUPLICATE

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Donnelly et al.

Serial No. 09/835,694

Filed: April 16, 2001

For: NUCLEIC ACID VACCINES AGAINST HUMAN  
INFLUENZA VIRUSArt Unit: 1636Examiner: Garvey, Tara L.Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR 1.97

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

12/15/2004 GWORDOF1 00000044 132755 09835694  
02 FC:1806 180.00 DA

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK &amp; CO., INC.

By J. Mark Hanel Date 12/10/04

**INFORMATION DISCLOSURE STATEMENT**

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

RELATED APPLICATION		
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE

If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

- ☐ the attached information is filed within three months of the filing date of the captioned case.
- ☐ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- ☒ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action or Notice of Allowance. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ the undersigned certifies that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- ☐ the undersigned certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,



By: J. Mark Hand

Attorney \_\_\_\_\_ For Applicant(s)

Reg. No. 36545

MERCK & CO., INC.

Patent Dept., RY60-30

P.O. Box 2000

Rahway, N.J. 07065-0907

(732)594-3905

Date: December 10, 2004

Sheet	1	of	8
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Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE</b>  <b>STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>			<b>COMPLETE IF KNOWN</b>		
			Application Number	09/835,694	
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			First Named Inventor	J.J. Donnelly	
			Group Art Unit	1636	
			Examiner Name	Garvey, Tara L.	
Sheet	2	of	8	Attorney Docket Number	18972PCA

NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	AA	Wang et al., 'Genetic Immunization: A Novel Method for Vaccine Development Against HIV...', Modern Approaches to New Vaccines, Including Prevention of Aids', p. 99 (9/16-9/29/92)
	AB	Liu et al. 'Immunization with DNA Encoding a Conserved Internal Viral...' Modern Approaches to New Vaccines, Including Prevention of Aids, p. 98 (9/16-9/29/92)
	AC	Rhodes et al., 'A Novel Method of Inducing Cellular and Humoral Immunity...' Modern Approaches to New Vaccines, Including Prevention of Aids', p. 91 (9/16-9/29/92)
	AD	Donnelly et al., 'Immunization with Influenza a Nucleoprotein...' Modern Approaches to New Vaccines, Including Prevention of Aids', p. 23 (9/16-9/29/92)
	AE	Parker et al. 'Intramuscular Vaccination of Plasmid DNA Containing...', Modern Approaches to New Vaccines, Including Prevention of Aids', p. 47 (9/16-9/29/92)
	AF	Rhodes et al., 'Injection of Expression Vectors Containing Antigen Genes...', Modern Approaches to New Vaccines, Including Prevention of Aids', p. 51 (9/16-9/29/92)
	AG	Friedman et al., 'Modulation of the Virulence of an H3N2 Influenza Virus...', Modern Approaches to New Vaccines, Including Prevention of Aids, p. 68 (9/16-9/29/92)
	AH	Edgington, S. 'PCR: Catching the Next Wave', Bio/Tech., 10: p 137-140 (1992)
	AI	Takahashi H., 'Induction of Broadly Cross-Reactive..', Science, 255: p 333-336 (1992)
	AJ	Cudd & Nicolau, 'Intracellular Fate of Liposome...', Biochimica et Biophysica Acta, 845, p 477-91 (1985)
	AK	Will et al., 'Infectious Hepatitis B Virus..' Proc. Natl. Acad. Sci.. 82: p 891-895 (1985)
	AL	Feitelson, et al. 'A Chronic Carrierlike..' J. of Virology, 62: No. 4, p 1408-1415 (1988)
	AM	Sureau et al. 'Cloned Hepatitis Delta..' J. of Virology, 63: No. 10, p 4292-4297 (1989)
	AN	Seeger, et al. 'In Vitro Recombinants of Group...', J. of Virology 61: No. 10, p 3241-3247 (1987)
	AO	Sprengel et al. 'Homologous Recombination between...', virolog, 159: p 454-456 (1987)

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\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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			Group Art Unit	1636	
			Examiner Name	Garvey, Tara L.	
Sheet	3	of	8	Attorney Docket Number	18972PCA

NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	AP	Sprengel et al. 'Cloned Duck Hepatitis B...' J. of Virology, 52: No. 3, p 932-937 (1984)
	AQ	Will et al., 'Cloned HBV DNA Causes Hepatitis...', Nature, 299: p 740-742 (1982)
	AR	Pestka et al. 'AntimRNA: Specific...', Proc. Natl. Acad. Sci., 81: p 7525-7528 (1984)
	AS	Dubensky et al. 'Direct Transfection of Viral..' Pro. Natl. Acad. Sci., p 7529-7533 (1984)
	AT	Felgner, et al., 'Cationic liposome-mediated transfection...' Nature, 337: No. 6205 p 387-388 (1989)
	AU	Brigham et al. 'Rapid Communication: In Vivo Transfection..', Am. J. Med. Sci., 298: p 278-281 (1989)
	AV	Furth et al., 'Gene Transfer into Somatic...' Analytical Biochem. 205: p. 365-368 (1992)
	AW	Seeger et al. 'The Cloned Genome of Group Squirrel...' Proc. Natl. acad. Sci., 81: p 5849-5852 (1984)
	AX	Grosse et al. 'Flow Cytofluorometric Investigation of the Uptake...', Bioch. et Biophysica Acta, 805: p 354-361 (1984)
	AY	Wu and Wu, 'Receptor-mediated Gene Deliver...' J. Bio. Chem. 263: NO. 29, p. 14621-14624 (1988)
	AZ	Wang and Huang, 'pH Sensitive Immunoliposomes Mediate...', Proc. Natl. Acad. Sci., 84: p7851-7855 (1987)
	AAA	Nicolau et al., 'In vivo Expression of Rat Insulin..' Proc. Natl. Acad. Sci. 80: p. 1068-1072 (1983)
	AAB	Felgner, P.L. 'Particulate Systems and Polymers...', Advanced Drug Delivery Reviews, 5: p. 1-25 (1990)
	AAC	Nabel, et al. 'Site-Specific Gene Expression Vivo...' Science, 249: p. 1285-1288 (1990)
	AAD	Brigham et al. 'Expression of Prokaryotic Gene...', Amer. J. Resp. Cell and Mol. Bio., 1: p. 95-100 (1989)

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Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	AAE	Holt, et al 'Lipofection of dDNAs in the Embryonic...' Neuron. 4: p 203-214 (1990)
	AAF	Tang et al. 'Genetic Immunization is aSimple..' Nature, 356: p. 152-154 (1992)
	AAG	Friedmann,T. 'Progress Toward Human Gene Therapy', Science 244: p. 1275-1281 (1989)
	AAH	Felgner, et al. 'Lipofection: A highly efficient, lipid-mediated...', Proc. Natl. Acad. Sci., 84: p. 7413-7417 (1987)
	AAI	Wolff, et al. 'Direct Gene Transfer into Mouse...' Science, 247: p. 1465-1468 (1990)
	AAJ	Louis and Verma, 'An Alternative Approach to Somatic...', Proc. Natl. Acad. Sci., 85: p. 3150-3154 (1988)
	AAK	Malone et al. 'Cationic Liposome-mediated RNA Transfection', Proc. Natl. Acad. Sci., 86: p. 6077-6081 (1989)
	AAL	Robinson et al. 'Use of Direct DNA Inoculations...', Abst. of Papers Pres. at 1992 meeting, p. 91-92 (1992)
	AAM	Physicians' Desk Ref., p. 1232-1234 (1993)
	AAN	Marantz Henig, R., 'New Vaccine Method...', NY Times Medical Science, pg C3 (1993)
	AAO	'Genes in a Bottle', Bio/Technology, 10: p. 132-136 (1992)
	AAP	Kaneda et al., 'Increased Expression of DNA...', Science, 243: p. 375-378 (1989)
	AAQ	Hansen et al. Strong Expression of Foreign Genes ...', FEBS, 290: p. 73-76 (1991)
	AAR	Lin et al. 'Expression of Recombinant Genes...' Circulation, 82: No. 6, p. 2217-2221 (1990)
	AAS	Gammel et al. 'Two Subtypes of Nucleoproteins...' Virology, 170: p. 71-80 (1989)

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NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	AAT	Townsend and Bodmer, 'Antigen Recognition by Class I...', Ann. Rev. Immunol. 7: p. 601-624 (1989)
	AAU	Jiao et al., 'Direct Gene Transfer into Nonhuman...' Human Gene Therapy, 3: p. 21-33 (1992)
	AAV	Chapman et al. 'Effect of Intron A from Human Cytomegalovirus...' Nucleic Acids Research, 19: No. 14, p. 3979-3986 (1991)
	AAW	Yang et al., 'In Vivo and In Vitro Gene Transfer...' Proc. Natl. Acad. sci. USA, 87: p. 9568-9572 (1990)
	AAX	DeWet et al. 'Firefly Luciferase Gene: Structure...', Molec. and Cell Biol. 7: No. 2, p. 725-737 (1987)
	AAY	Johnston, S.A. 'Biostotic Transformation: Microbes to Mice', Mature 346: p. 776 (1990)
	AAZ	Germain, R. 'The Ins and OUtS of Antigen...', Nature, 322: p. 687-689 (1986)
	ABA	Bevan, M. 'Class Discrimination in the World of Immunology', Nature, 325: p. 192-194 (1987)
	ABB	Acsadi, et al. 'Human Dystrophin Expression in MDX....' Nature, 352, p. 815-818 (1991)
	ABC	Giguere et al. 'Identification of a Receptor for the Morphofen Retinoic Acid', Nature, 330: p. 624-629 (1987)
	ABD	Ono et al., 'Plasmid DNAs Directly Injected...', Neuroscience Ltrs., 117: p. 259-263 (1990)
	ABE	Whang et al., 'Expression of the Epstein-Bar Virus...', J. of Virology, 61: No. 6, p. 1796-1807 (1987)
	ABF	Gorman et al., 'Evolution of Influenza A Virus Nucleoprotein...' J. of Virology, 65: No. 7, p. 3704-3714 (1991)
	ABG	Wu et al., 'Targeting Genes: Delivery and Persistent Expression...', The J. of Biol. Chem., 264: No. 29, p. 16985-16987 (1989)
	ABH	Ulmer et al. 'Heterologous Protection Against Influenza...', Science, 259: p. 1745-1749 (1993)

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NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	ABI	Cohen,J., 'Naked DNA Points Way to Vaccines', Science, 259: p.1691-1692 (1993)
	ABJ	Friend, T., 'Gene Therapy May Aid Heart Ailments', USA Today, p. 1-D, Feb. 11 (1991).
	ABK	Soriano P., et al. 'Targeted and Nontargeted Liposomes...', Proc. Natl. acad. Sci.: 80: p. 7128-7131 (1983)
	ABL	1993 Conference, Washington, D.C. Bioeast, p. 57-58 Jan. 24-27 (1993)
	ABM	Waldholz, M. 'Merck Team Develops a New Type...', Wall Street Jour. Tech & Med. Section, March 19, (1993)
	ABN	Wolff et al. 'Long-Term Persistence of Plasmid DNA...', Human and Molec. Gen., 1: No. 6, p. 363-369 (1992)
	ABO	Wolff and Lederberg, Human Gene Therapy, Vol. 5, pp. 469-480 (1994)
	ABP	Yakubov, et al., 'Mechanism of Oligonucleotide Uptake by Cells...', Proc. Natl. acad. sci, Vol. 86 pp. 6454-6458, (1989)
	ABQ	Selden, et al., 'Expression of the Human Growth Hormone...', Proc. Natl. Acad. Sci., Vol. 85, pp. 8241-8245 (1988)
	ABR	Loyter et al., 'Mechanisms of DNA Uptake by Mammalian Cells...', Proc. Natl. Acad. Sci., Vol. 79, pp. 422-426 (1982)
	ABS	Chen et al. 'High-Efficiency Transofrmation of Mammalian Cells', Mol. cell. Biol., Vol 7, No. 8, 1987
	ABT	Zhu et al. 'Systemic Gene Expression After Intravenous DNA...', Science, Vo. 261, 1993
	ABU	Wang, et al. 'Gene Inoculation Generates Immune Responses...', Proc. Natl. Acad Sci., Vo. 90, pp 4156-4160, May 1993
	ABV	Cheng et al. 'In Vivo Promoter Activity and Transgene Expression...', Proc. Natl. acad. Sci., Vol 90, pp 4455-4459, 1993
	ABW	Nicolau et al, 'Liposomes as Carriers for In Vivo Gene Transfer and Expression', Methods in Enzymology, Vol. 149, pp 157-177

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	ABX	Maninno et al., 'Liposome Mediated Gene transfer', Biotechniques, Vol. 6, No. 7, pp 682-690, 1988
	ABY	Berton et al. 'Antigenic Structure of the Influenza B Virus Hemagglutinin..', J. of Vir., Vo.. 52, No. 3, pp 919-927, 1984
	ABZ	Rota et al. 'Comparison of the Immune Response to Variant Influenza...', Virology, Vol. 161, No. 2, pp 269-275, 1987
	ACA	Rodriguez et al. 'Mammalian Expression Vectors, Vectors, pp 467-492, 1988
	ACB	Physician's Desk Reference, 46th Ed., Medical Economics, NJ, pp 1204-1206, 1992
	ACC	Brown et al., 'Assessment of Retrovirus-Expressed Nucleoprotein', Avian Diseases, Vol. 35, pp 515-520, 1992
	ACD	Benvenisty and Reshef, 'Direct Introduction of Genes into Rats..' Proc. Natl. Acad. Sci., 83: p 9551-9555 1986
	ACE	Verma, I., 'Gene Therapy', Scientific American, p 68-84, 1990
	ACF	Luckow and Schultz, 'Cat Constructions with Multiple Unique...', Nucleic Acids Research, p. 5490, 1987
	ACG	Kitsis, et al. 'Hormonal Modulation of a Gene Injected..', Proc. Natl. Acad. sci. USA, 88: p. 4138-4142, 1991
	ACH	Crystal, R.G., 'Transfer of Genes to Humans: Early Lessons and Obstacles to Success', Science, Vol. 270, pp 404-410, 1995
	ACI	Rota et al. 'Comparison of inactivated, live and recombinant DNA vaccines against influenza virus in a mouse model', Virus Research, Vol. 16, pp 83-94, 1990
	ACJ	Air et al. 'Conservation and Variation in Influenza Gene Sequences', UCLA Symp. Mol. Cell Biol., Vol. 21, pp 29-44, 1981
	ACK	Whalen R.G. 'DNA Vaccines for Emerging Infectious Diseases: What if?', Emerging Infectious Diseases', Vol 2, No. 3, pp 168-175, July-Sept 1996

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